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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITIGATION	Case No. 13-md-2452-AJB-MDD As to all related and member cases **PROCEDURES FOR PRODUCTION OF ELECTRONICALLY STORED INFORMATION**

This order relates to the production of documents and supplements all other discovery rules and orders as between defendant Eli Lilly and Company ("Lilly"), and all plaintiffs in this litigation. It streamlines Electronically Stored Information ("ESI") production to promote a "just, speedy, and inexpensive determination" of this action, as required by the Federal Rules of Civil Procedure. This Order shall be read consistently with the Court's January 9, 2014 Order on Discovery Dispute Protocols for Electronically Stored Information (Doc. 257).

A. <u>Format of Production</u>

1. The Parties shall produce electronic documents in a single-paged Tagged Image File format ("TIFF") with extracted text with an accompanying load file to indicate the location and unitization of the TIFF files. The Parties will also produce hard copy documents in single-paged Tagged Image File format ("TIFF").

2. Each page of a produced document shall have a legible, unique page identifier ("Bates Number"), and confidentiality legend (where applicable), on the face of the image at a location that does not interfere with the information from the source document.

3. To the extent possible, Lilly will provide the following metadata fields:

   a. Beginning bates number
   b. Ending bates number
   c. Beginning attachment number
   d. Ending attachment number
   e. Attachment count (email)
   f. Attachment name (email)
   g. Custodian/Source
   h. Author/From
   i. Document type
   j. Subject
   k. Recipient
   l. CC
   m. BCC
   n. Sent date
   o. Received date
   p. Create date
   q. Last modified date

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1   r. DocExt

2   s. File name

3   t. File path

4   u. Native file link

5   v. Text path

6   w. Importance

7   x. File size

8   y. Page count

9   z. Redacted

10 This list of fields does not create any obligation to create or manually code fields that

11 are not automatically generated by the processing of the ESI, that do not exist as part

12 of the original metadata of the document, or that would be burdensome or costly to

13 obtain. The Custodian/Source metadata field shall be provided for all documents

14 produced.

15   4. In scanning paper documents, distinct documents shall not be merged into a

16   single record, and single documents shall not be split into multiple records

17   (*i.e.*, paper documents should be logically unitized). Parent-child

18   relationships (the association between an attachment and its parent

19   document) shall be preserved. Original document orientation shall be

20   maintained (i.e., portrait to portrait and landscape to landscape).

21   5. Excel spreadsheets that do not require redaction shall be produced in native

22   format. PowerPoint presentations that do not require redaction may be

23   produced in native format or in TIFF. Any document produced in native

24   format will have a corresponding place holder TIFF image for these records

25   bearing the legend "This document produced in native file format only."

26   Prior to the production of native documents, the Parties will reach agreement

27   on the format and use of such native documents. Other document formats

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INFORMATION

1   that present imaging problems shall promptly be identified, and the Parties

2   shall meet and confer to attempt to resolve the problems.

3   6. The mere production of ESI in this litigation as part of a larger production

4   shall not itself constitute a waiver for any purpose.

5   7. Pursuant to Federal Rule of Evidence 502(d) and the governing Protective

6   Order in this case, the production of a privileged or work product protected

7   document is not a waiver in the pending case or in any other federal or state

8   proceeding.

9   8. The Parties are not required to produce exact duplicates of electronic

10   documents stored in different locations. Lilly may globally de-duplicate

11   identical ESI, which will be determined as follows:

12   (i)   Electronic files will be de-duplicated based upon calculated SHA1

13   values for binary file content. File contents only will be used for

14   SHA 1 value calculation and will not include operating system

15   metadata (filename, file dates) values.

16   (ii)   Messaging files will be de-duplicated based upon SHA 1 values for

17   the message family, including parent object and attachments. The

18   following fields will be used to create the unique value for each

19   message: BCC; CC: To: Date Sent; From; Subject; AttachmentCount;

20   Total Attachment Size. Messaging materials will be de-duplicated at

21   a family level, including message and attachment(s).

22   If Lilly de-duplicates identical ESI, Lilly shall provide custodian

23   associations in a semi-colon delimited overlay file that includes duplicate

24   custodian name information and related source file paths for the duplicate

25   custodians. The overlay files shall be produced after every production and

26   shall be regularly updated to account for rolling productions. The parties

27   shall produce documents on CD, DVD, or hard drives.

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9. No party has an obligation to make its production text-searchable; however, if a party's documents exist in text-searchable format, then such documents shall be produced in a text-searchable format at no cost to the receiving party.

10. For each document containing searchable text, a single text file shall be provided along with the image files and metadata. The text file name shall be the same as the Bates number of the first page of the document. File names shall not have any special characters or embedded spaces. Electronic text must be extracted directly from the native electronic file unless the document was redacted, an image file, or a hard copy document. Subject to paragraph B.9, in these instances, a text file shall be created using OCR and shall be produced in lieu of extracted text.

11. Absent a showing of good cause, no party need restore any form of media upon which backup data is maintained in a party's normal or allowed processes, including but not limited to backup tapes, disks, SAN, and other form of media, to comply with its discovery obligations in the present case. It will be presumed, although either party may seek to rebut that presumption, that costs for production from a backup or archive, to the extent it is deemed necessary, will be paid by the party making the request.

12. Absent a showing of good cause, non-transcribed voicemails, and PDAs are deemed not reasonably accessible and need not be collected and preserved.

13. When processing ESI, EST shall be selected as the time zone.

14. Objects embedded in Microsoft Word and .RTF files will be extracted as separate documents and produced as attachments to the document.

15. Compression file types (i.e., .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual folders and/or files.

16. Audio files and video files shall be produced in native format with the source file path provided.

17. Any documents that are replaced in later productions shall be clearly designated as such, by appending an " R" to the production prefix. When a party produces a replacement production indicated by "R," the receiving party must discard or return to the producing party all copies, including working copies, of the original, replaced image.

18. Any native files that are produced shall be produced with the source file path provided, as well as all extracted text and applicable metadata fields set forth in this order.

19. Documents with dynamic fields for file names, dates, and times will be processed to show the field code (e.g., "[FILENAME]" or "[AUTODATE]"), rather than the values for such fields existing at the time the file is processed.

20. The Parties will meet and confer, as necessary, regarding potentially relevant structured data sources.

B. Production of Custodial Files

1. Upon agreement of the parties, Lilly shall identify up to eight custodians, keeping in view the pleaded claims and defenses in this litigation, to Plaintiffs' counsel. Lilly shall begin producing responsive, non-privileged, reasonably accessible documents, on a rolling basis, from the custodial files of these custodians. This paragraph does not relieve Lilly from its obligation to either respond or object to Plaintiffs' production requests made in, or applicable to, this MDL. Lilly will use search terms, agreed upon by the parties and attached as Exhibit A hereto, to cull collected electronic data. The parties may agree to modify these search terms.

2. Lilly will notify Plaintiffs when the production of a custodial file is substantially complete. Upon substantial completion of the production of the

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custodial files of the above-referenced custodians, the parties will meet and confer regarding the production of additional custodial files, if any. As necessary, the parties will meet and confer with respect to the process by which supplemental custodial file productions will be made, subject to agreement of the parties. If Plaintiffs elect to take the deposition of a custodian prior to receiving notice that the production of the custodian's documents is substantially complete, Plaintiffs will not be entitled to further depose that witness on the grounds that the document production was not complete.

3. This order supersedes all pending or previously served instructions pursuant to Requests for Production directed to Lilly, and governs all pending or future instructions accompanying Requests for Production, Requests for Admission, Interrogatories, and deposition notices directed to Lilly.

C. Technical Specifications

1. All TIFF-formatted documents will be single page, Group 4 TIFF at 300 x 300 dpi resolution and 8.5 x 11 inch page size, except for documents that in the producing party's reasonable judgment require a different resolution or page size. If a color image is produced in black and white, the receiving party may request the producing party to produce the original, color image. After receiving such a request for color production, the parties will meet and confer on a reasonable and cost-effective means of providing the requested documents.

2. There will be two Load/Unitization files accompanying all productions. One will be the Image load file and the other will be the Metadata load file.

3. Specifications for the image load files will be the following:

(i) Every Document referenced in a production image load file shall have all corresponding images, text, and data logically grouped together in a directory structure with a common key to properly load the data.

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   (ii) Documents shall be produced in only one image load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.

   (iii) The name of the image load file shall mirror the name of the delivery volume, and should have an .lfp, .opt or .dii* extension (e.g., ABC00l.lfp). The volume names shall be consecutive (i.e., ABC001, ABC002, et. seq.). If a .dii file is produced, the accompanying metadata load file shall be separate from the .dii file and not contained within the .dii file.

   (iv) The load file shall contain one row per TIFF image.

   (v) Every image in the delivery volume shall be contained in the image load file.

   (vi) The image key shall be named the same as the Bates number of the page. Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.), i.e., a separate volume shall be created for each piece of media delivered.

4. Specifications for the metadata load files will be the following:

   (i) The metadata load file shall use the following delimiters:

- Column Delimiter: Pipe - | (ASCII 124) or (ASCII 020)
- Text Qualifier: Caret - ^ (ASCII 94) or þ (ASCII 254)
- New line: Registered sign - ® (ASCII 174)
- Example: þPRODBEGþþPRODENDþþPRODBEGATTþ

   (ii) Data for documents shall be produced in only one data load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.

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     (iii)   The first record shall contain the field names in the order of the data set forth in the Metadata.

     (iv)   All date fields shall be produced in "mm/dd/yyyy hh:mm:ss AM" format.

     (v)   A carriage-return line-feed shall be used to indicate the start of the next record.

     (vi)   Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.); a separate volume shall be created for each piece of media delivered.

     (vii)   The name of the metadata load file shall mirror the name of the delivery volume, and shall have a .dat, .csv or .txt extension (i.e., ABC00l.dat).

     (viii)   The volume names shall be consecutive for each produced source. (i.e., ABC00l, ABC002, et. seq.).

D. Costs

While each party expressly reserves its rights to seek costs relating to this litigation, including the costs of producing documents, initially each party will bear the costs to process and review its own documents and readily accessible ESI. To the extent any party requests data that is not readily accessible, subject to Paragraph C.11, the parties shall comply with the Federal Rules of Civil Procedure in determining whether the inaccessible data is to be produced, including the costs to process or review unique or non-standard data. The parties shall confer concerning inaccessible material, including inaccessible ESI, prior to seeking the Court's assistance.

E. Protective Order

All documents that have been or will be produced by the parties will be subject to the terms of the Protective Order entered in this litigation.

F. Predictive Coding

The parties agree that Lilly may, but is not required to, use predictive

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1   coding in connection with the review of documents in this litigation.

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3   IT IS SO ORDERED.

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5   DATED: April 21, 2014   _____
                                      Honorable Mitchell D. Dembin
6   United States Magistrate Judge

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Exhibit A

Lilly Search Terms

Qualifiers
"21 773" OR "21773" OR "21,773" OR "21-773" OR "021 773" OR "021773" OR "021,773" OR "021-773" OR "N21 773" OR "N21773" OR "N21,773" OR "N21-773" OR "N021 773" OR "N021773" OR "N021,773" OR "N021-773" OR "NDA21 773" OR "NDA21773" OR "NDA21,773" OR "NDA21-773" OR "NDA021 773" OR "NDA021773" OR "NDA021,773" OR "NDA021-773" OR "21 919" OR "21919" OR "21,919" OR "21-919" OR "021 919" OR "021919" OR "021,919" OR "021-919" OR "N21 919" OR "N21919" OR "N21,919" OR "N21-919" OR "N021 919" OR "N021919" OR "N021,919" OR "N021-919" OR "NDA21 919" OR "NDA21919" OR "NDA21,919" OR "NDA21-919" OR "NDA021 919" OR "NDA021919" OR "NDA021,919" OR "NDA021-919" OR "57 725" OR "57725" OR "57,725" OR "57725" OR "057 725" OR "057725" OR "057,725" OR "057-725" OR "I57 725" OR "I57725" OR "I57,725" OR "I57-725" OR "I057 725" OR "I057725" OR "I057,725" OR "I057-725" OR "IND57 725" OR "IND57725" OR "IND57,725" OR "IND57-725" OR "IND057 725" OR "IND057725" OR "IND057,725" OR "IND057-725" OR "67 092" OR "67092" OR "67,092" OR "67-092" OR "067 092" OR "067092" OR "067,092" OR "067-092" OR "I67 092" OR "I67092" OR "I67,092" OR "I67-092" OR "I067 092" OR "I067092" OR "I067,092" OR "I067-092" OR "IND67 092" OR "IND67092" OR "IND67,092" OR "IND67-092" OR "IND067 092" OR "IND067092" OR "IND067,092" OR "IND067-092" OR "68 703" OR "68703" OR "68,703" OR "68-703" OR "068 703" OR "068703" OR "068,703" OR "068-703" OR "I68 703" OR "I68703" OR "I68,703" OR "I68-703" OR "I068 703" OR "I068703" OR "I068,703" OR "I068-703" OR "IND68 703" OR "IND68703" OR "IND68,703" OR "IND68-703" OR "IND068 703" OR "IND068703" OR "IND068,703" OR "IND068-703" OR "77 359" OR "77359" OR "77,359" OR "77-359" OR "077 359" OR "077359" OR "077,359" OR "077-359" OR "I77 359" OR "I77359" OR "I77,359" OR "I77-359" OR "I077 359" OR "I077359" OR "I077,359" OR "I077-359" OR "IND77 359" OR "IND77359" OR "IND77,359" OR "IND77-359" OR "IND077 359" OR "IND077359" OR "IND077,359" OR "IND077-359" OR "78 919" OR "78919" OR "78,919" OR "78-919" OR "078 919" OR "078919" OR "078,919" OR "078-919" OR "I78 919" OR "I78919" OR "I78,919" OR "I78-919" OR "I078 919" OR "I078919" OR "I078,919" OR "I078-919" OR "IND78 919" OR "IND78919" OR "IND78,919" OR "IND78-919" OR "IND078 919" OR "IND078919" OR "IND078,919" OR "IND078-919" OR "10 7815" OR "107815" OR "10,7815" OR "10-7815" OR "I10 7815" OR "I107815" OR "I10,7815" OR "I10-7815" OR "IND10 7815" OR "IND107815" OR "IND10,7815" OR "IND10-7815" OR *byetta OR byetta* OR *bydureon OR bydureon* OR exenatid* OR AC2993 OR exendin OR Alliance OR Nuzendis OR QW OR EQW OR LAR OR "2 993" OR "02 993" OR "02993" OR "02,993" OR "02-993" OR 2993 OR "2,993" OR "2-993" OR C184H272N50060S OR "LLY214 8568" OR "LLY2148568" OR "LLY21,48568" OR "LLY21-48568" OR "LSN214 8568" OR "LSN2148568" OR "LSN21,48568" OR "LSN21-48568" OR "214 8568" OR 2148568 OR "21,48568" OR "21-48568" OR "141 732765" OR 141732765 OR "141,732765" OR "141-732765"

Search Terms
acinar* or protease
Actos
ADA
Adenom*
"adverse event*" or "serious event*" or "adverse reaction*"
(advertisement* or ad or ads) w/5 (consumer* or DTC or DTP or HCP)
AER or AERs or AE or AEs or SAE or SAEs or OAERS or FAERS or FDAAERS
AkdA
Alexandra /2 Butler
aloglipti*
"alpha glucosidase"
amylase
anaphylaxis or anaphylactic
Animal
antidiabetic
apoptosis
Avandia
Bayesian
Belinda /2 Gier
Belinda /2 Schulda
benefit* /5 risk*
"beta cell" or "c cell"
biliary
"Bonner-Weir"
"Butler et al"
Butler w/100 (ductal)
Bydureon w/100 (CEA OR MCN OR thyroid)
"c cell" or "c-cell"
"CA 19-9"
CAC or "Carcinogenicity Assessment Committee"
campaign* /5 (consumer* or DTC or DTP or HCP)
Cancer*
Carci*
Carpenter
case /3 (report* or assessment*)
CEA w/100 pancr*
"cfr 314"
commercial* /5 (consumer* or DTC or DTP or HCP)
committee /3 (advisory or steering or assessment or bioethics or "ae-pc" or surveillance or chmp or endpoint or data* or executive or ethics or event* or adjudication or ethics or oversight or pancreatitis or physician or plan* or research or safety or policy or label* or quality)
"complaint investigat*" or "complaint coordinator*"

complaint team*
ct w/5 (scan* OR imag* OR show*)
"data safety monitoring board"
data* /2 (surveillance or ukpds or trial or claims or covariate or core or laboratory or spontaneous or lipase or agonist or safety)
data* /5 (nonclinical or "non-clinical")
data* /5 (preclinical or "pre-clinical")
DDMAC or OPDP
"dear doctor" or "dear dr" or "dear healthcare" or DHCP
Diabetes
Diabeti*
"dipeptidyl peptidase"
Disproportionality
"Division of Diabetes, Endocrinology, and Metabolic Diseases" or "DEM"
"DNN"
"DP-IV"
DPP-4 or DPPIV or DPP4 or DPP-IV or "DDP IV" or "DDP IV's" or "DPP 4" or "DPP 4's"
Drucker
"drug safety monitoring" or dsmb
ductal /2 (cell or obstruction or turnover or replication)
ductal /5 bil*
EBGM* or "eb05" or EGBM
Elashoff
EMEA
endocrine
epidemiological /2 (data* or analysis)
ERCP
exocrine
expert* /3 (panel* or speaker* or report* or consultant* or roundtable or committee or preclinical or safety or internal or external)
FDA*
Gale
Galvus
Genotox*
Gier
glipti*
gliptin*
glitaz*
"GLP-1" or "GLP1" or "GLP 1" or "GLP I"
glucago*
group /3 (safety or study or complaint or data* or biometric* or treatment or research or evaluation or endpoint or outcome* or protocol or advisory or statistics or trial or writing or quality)
Health Hazard Evaluation* or hhe*
hypersensitivity reaction*

hypoglycemi*
IIT or "Investigator Initiated Trial"
incidence rate*
increti*
intraductal OR (intra w/2 ductal)
IPMN
Janumet w/100 (CEA OR MCN OR thyroid)
Januvia w/100 (CEA OR MCN OR thyroid)
jaundic*
Jentadueto
Kahn
Kazano
key messag*
kol or kols or champion* or "opinion leader*" or "thought leader*"
Kombiglyze
label* /15 ("black box" or "blackbox" or warn*)
label* /5 (chang* or extension* or update*)
"lactic acidosis"
Lesion
level 3 complaint*
linaglipti*
Lipase
(literature or brochure*) /5 (consumer* or DTC or DTP or HCP)
Malig*
marketing report*
Matteo /2 Monami
matvey*
Mechanistic
medullary
"meta analysis" or "meta-analysis"
Metaplasi*
metaplatic
Metast*
mfr /3 (report or number or labeler)
MGPS or "Mult-item Gamma Poisson Shrinker"
Michael /2 Nauck
mid* w/2 epigastric
mimeti*
monitor* /3 (safety or event* or guideline*)
monkey OR primate* or monkie* or monke*
mouse OR mice
MSD
Murine
"National Cancer Institute" or "NCI"

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"National Institute of Diabetes and Digestive and Kidney Diseases"
"National Institute of Health" or "NIH"
Neopl*
Nesina
"Network for Pancreatic donors with Diabetes" or "NPOD"
NIDDK
nonclinical tox*
Onglyza
Oseni
panc*
"Pancreatic Cancer Action Network" or "PCAN"
PanIN
pdg
"Peptide-1" or "Peptide 1" or peptidase
"periodic report*" or pmr or psur*
Peter /2 Butler
Pioglitazone
*plasia
plasma /3 (concentrat* or glucose)
"post marketing" or "post-marketing" or "post market"
"postmarketing safety"
postprandial /3 (glucose or plasma)
"pre-cancerous" or precancerous
preclinical tox*
"press release*" or "press-release*"
"product complaint" /5 ("evaluation group*" or "sub-team*")
"product safety committee"
prolifer*
prolifer* w/10 (duct* OR cell*)
PRR or aPRR or "Proportional Reporting Ratio"
"quality assurance" or QA or "quality control" or QC or SOP or SOPs
rat OR rats
receptor agonist*
regulatory /10 (fda or report* or contact*)
REMS
result* /5 (nonclinical or "non-clinical")
result* /5 (preclinical or "pre-clinical")
"Risk Evaluation and Mitigation Strategy"
Roseglitazone
Rosiglitazone
Rosol
"safety core" /2 (group or team)
safety profile*
Sargartz

saxaglipti*
SCA
SCD
Sedo
Sidney /2 Wolfe or "Dr Wolfe"
Signal
sitagliptin w/100 (CEA OR MCN OR thyroid)
Skyler
Sonal /2 Singh
"speaker* bureau" or "round table" or roundtable
speaker /2 (dinner or lunch or breakfast)
"standby statement*" or "stand-by statement*"
strateg* /5 (consumer* or DTC or DTP or HCP)
stud* /5 (nonclinical or "non-clinical")
stud* /5 (pharma* or toxic* or design* or literature or population or medication* or ongoing or foreign or extension or control* or completed or cohort or safety or cancer)
stud* /5 (preclinical or "pre-clinical")
T2DM
team /3 (advisory or label* or review* or leadership or project or statistics or safety or risk* or biostats or brand or operational or ops)
team /3 (consult* or develop* or writing or escalation or plan* or market* or tactical)
team /3 (data* or mining or clinical or medical or cmc or epidemiology or study or pharmaco* or surveillance or toxicolog* or quality or QA)
thiazolidinedione*
Tradjenta
tumor*
"Type 2"
tzd
"Williams-Herman"
"a cell"
"⬚ cell"
janumet*
*janumet
Januvi*
*januvi
metformi*
*metformi
sitaglip*
*sitaglip
Byetta w/100 (CEA OR MCN OR thyroid)
etformin
Exenatide w/100 (CEA OR MCN OR thyroid)
Juvisync
Liraglutid*